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EXAMINER

KOLKER, DANIEL E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1649

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/785,158             | HINZ, MARTIN C.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Daniel Kolker          | 1649                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37-53 is/are pending in the application.
- 4a) Of the above claim(s) 11, 16-18, 21-23, 28-32 and 46-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-15, 19, 20, 24-27, 33-35, 37-45 and 51-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 and 37-53 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/27/04, 11/24/04, 12/14/05, 1/13/06,</u>                                 | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's remarks and amendments filed 2 May 2006 have been entered. Claim 36 is canceled; claims 1 – 35 and 37 – 53 are pending.

### ***Election/Restrictions***

2. Applicant's election without traverse of Group II, and species B (serotonin) and F (obesity) in the reply filed on 2 May 2006 is acknowledged.

Applicant listed claims 28 and 46 as reading on the elected invention. However neither claim recites either of the elected species, and applicant also requested withdrawal of the claims. As the claims were requested to be withdrawn, are listed on the current version of the claims as (withdrawn), and the examiner is unable to find any elected species in claims 28 and 46, they will be withdrawn.

3. Claims 11, 16 – 18, 21 – 23, 28 – 32, 46 – 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2 May 2006.
4. Claims 1 – 10, 12 – 15, 19 – 20, 24 – 27, 33 – 35, 37 – 45, and 51 – 53 are under examination.

### ***Information Disclosure Statement***

5. The information disclosure statements have been considered. Note that on p. 2 of the IDS filed 10 April 2006, the reference "Anchors Book" has been crossed out. No date has been provided and thus the examiner cannot determine if the reference is prior art.

### ***Claim Objections***

6. Claim 1 is objected to because of the following informalities: it has a typographical error, "subject' -s". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1 – 10, 12 – 15, 19 – 20, 24 – 27, 33 – 35, 37 – 45, and 51 – 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claimed methods are indefinite for many reasons. Claim 1 recites the phrase “determining a subject’s health status with respect to neurotransmitter dysfunction”. It is entirely unclear what this phrase means. Does it mean determining whether or not the subject is alive, as that is related to neurotransmitter function and dysfunction? Does it mean determining whether or not the subject has depression, Parkinson’s disease, or epilepsy, each of which are well-known to be characterized by improper levels of neurotransmitters? Does it mean determining actual levels of neurotransmitters within the synapses? The use of the phrase “health status” is particularly ambiguous, because anything can be some sort of health status, from completely healthy to dead. Furthermore claim 4 recites “wherein the health status is determined with respect to the group of dysfunction consisting of obesity” and other diseases. Again, it is entirely unclear what it means for a health status to be determined with respect to any of these conditions.

Claims 5 – 7 recite the phrase “wherein the step of assaying is implemented via the subject’s” serum, saliva, and urine fluid. This term is also unclear and incomplete. The skilled artisan would not be able to determine what it means for a step of assaying to be implemented via a certain fluid. Assays are performed on certain substrates or fluids, but that does not mean they are implemented via those fluids. The word “via” means “by way of” but the remainder of the claims do not direct the artisan which way the step of assaying should be implemented. Furthermore the body of the claim does not refer back to the preamble of either this claim or the base claim, so it is unclear how the method is accomplished.

Claim 12 recites “wherein the neurotransmitter is serotonin and catecholamine”. Similarly, claim 44 recites “a combination of serotonin and catecholamine”. First, a neurotransmitter cannot be both serotonin and something else, it has to be one or the other. Second, catecholamine is not a neurotransmitter, but rather refers to a group of neurotransmitters including epinephrine, norepinephrine, and dopamine. Thus the skilled artisan could not determine how the neurotransmitter is serotonin and catecholamine.

Claim 13 recites “wherein the at least one neurotransmitter status point is a baseline reference point”. The term “baseline reference point” is vague and indefinite. A skilled artisan

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could not determine the metes and bounds of this claim, as it is unclear what makes a point a baseline reference point. Additionally claim 14 recites "wherein the baseline reference point is within a reference range". As no values at all are recited in the claim, this could be anything. Again a skilled artisan could not determine the metes and bounds of this claim, because it is entirely unclear what constitutes "a reference range". Similarly, claim 19 recites "wherein the baseline reference point is further within an optimal range". As no values at all are recited in the claim, this could be anything. Again a skilled artisan could not determine the metes and bounds of this claim, because it is entirely unclear what constitutes "an optimal range". Claim 24 is limited to those cases where the baseline reference point is outside a reference range, but since the claim does not recite any range it is impossible to determine whether or not the value is within or outside the range. Likewise, claims 25 – 26 are drawn to therapeutic points, but it is unclear either what constitutes a therapeutic point or how a skilled artisan would know whether or not the at least one therapeutic point is within a therapeutic range, as recited in claim 26.

Claim 33 requires administration and "graphing neurotransmitter level over time", which is indefinite. What is to be graphed? Is it the level of neurotransmitter administered, or is it the level of neurotransmitter assayed? What does it mean for it to graphed "over time"? Does that mean that the X-axis represents time, or alternatively does it mean that every time that the assay step is performed the "neurotransmitter level" should be graphed? Claim 34 requires the artisan to determine "an inflection point" on the graph. However this term is not explicitly defined in the specification. It is unclear whether it refers to a complete lack of change in the slope of a curve, or if the slope of the curve is infinite. Furthermore since it is unclear what the X- and Y-axes are on this graph, it is unclear what value the inflection point has. Finally, if the slope of the graph never changes, how could one determine an inflection point? Claim 35 depends from claims 33 and 34, but requires that "the inflection point is used to determine the therapeutic range." The claim does not tell the artisan how to perform the method. There is no indication whether the inflection point is above, below, or identical to the therapeutic range. The term "inflection point" in claims 34 – 35 is a relative term which renders the claim indefinite. The term "inflection point" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As set forth above, the specification does not define an inflection point or how to determine it.

Claim 37 is indefinite because it requires that a second assay be administered to a subject. The specification does not teach the artisan how to administer an assay of a body fluid to a subject. It is unclear whether the assay is to be performed on the body fluid, or whether the body fluid should be administered to the subject, or whether the reagents for the assay should be administered to the subject. Furthermore, the claim requires that the artisan determine whether or not the neurotransmitter level is "within a predetermined therapeutic range" but there is no indication of what said range actually is.

Claim 38 is indefinite for all the same reasons that claim 37 is indefinite, and furthermore because it recites "wherein health status is determined". As explained above, it is unclear what this phrase means, and thus a skilled artisan could not determine the metes and bounds of this claim.

Claims 39 – 42 are indefinite for all the reasons that the claims from which they depend are indefinite, and furthermore because they recite "wherein the step of assaying is implemented via the subject's" serum, saliva, and urine fluid. See the more detailed explanation in the rejection of claims 5 – 7, above. It is unclear how a step is implemented via a fluid.

Claim 51 is also indefinite because it recites the steps of "graphing neurotransmitter level over time" and determining "an inflection point" and "wherein the inflection point is used to determine the therapeutic range." The reasons why each of these phrases are indefinite are explained above in the rejections of claims 33 – 35.

Claim 52 is indefinite for all the reasons claim 51 is indefinite, and further because it recites the limitation "the therapeutic range". The claim does not recite the therapeutic range, so it could be anything.

Claim 53 is indefinite for many of the reasons set forth above. First, it recites the phrase "or the like", which is itself indefinite. See MPEP § 2173.05(b), particular subsections C and F. Recitation of the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). Second, it recites the phrase "based on catecholamine-serotonin neurotransmitter dysfunction". This term is very confusing. What does it mean for something to be "based on" some sort of dysfunction? Additionally, it is unclear whether this requires that all catecholamines have some sort of dysfunction, or that serotonin have some dysfunction, or that any one of the catecholamines have a dysfunction, or any particular combination of these. Part (c) of the claim requires that an

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assay be administered "of a body fluid". It is unclear how to administer an assay, as set forth in the rejection of claim 37, above. Finally, part (d) is indefinite for all the reasons relating to graphing, as set forth in the rejections of claims 33 – 35 above.

The remaining claims are rejected for depending from a rejected base claim.

8. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "the administration step" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 3, 7 – 10, 13 – 14, 19, and 24 – 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Curtius et al. (U.S. Patent 4,774,244, issued 27 September 1988).

Curtius teaches measurement of serotonin in the urine of a patient with inhibited depression (see Table 1). Claim 1 requires that the artisan determine the subject's "health status with respect to neurotransmitter dysfunction". As Curtius teaches that the patient has "inhibited depression" and correlates this with the level of several neurotransmitters including serotonin, this reasonably meets the step of determining the subject's health status with respect to neurotransmitter dysfunction. Curtius also teaches the determination of serotonin, which meets the limitation of "performing an assay" and determining a neurotransmitter status point as recited in claim 1. Curtius presents the results, and while he does not use the exact words "neurotransmitter status point" how he defines the result does not affect the patentability of the claim. The prior art reference teaches every step recited in claim 1 and thus anticipates the claimed method.

Claim 2 is rejected because the subject was a human. See Curtius column 3 lines 3 – 12, where the author teaches that "a man aged 62 with idiopathic Parkinson's disease" was

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studied. Claim 3 is rejected because the subject had been examined and determined to have Parkinson's disease. Claim 7 is rejected because the urine was assayed. Claim 8 is rejected because urine samples were collected at 0, 2, 4, 8 – 10, and 12 hours. While the reference is silent as to the patient's bedtime and the actual time of collection, any one of these points reasonably falls 5 – 6 hours before the patient's bedtime. For instance, if the patient's bedtime is 11PM, and the first sample is collected at 9 AM, then 8 – 10 hours later is 5PM – 7 PM, which is within the range of 5 – 6 hours before the bedtime. Claim 9 is rejected because the results are expressed in umoles of neurotransmitter per mole of creatinine (see table). While this is not "per gram of creatinine" as recited in claim 9, the values are easily converted and said conversion does not distinguish the invention of claim 9 from the prior art. Claim 10 is rejected because serotonin was measured. Claims 13 and 14 are rejected because they require no steps beyond claim 1 and the specification does not disclose what constitutes either a baseline reference point or a reference range. Furthermore as shown in Table 1 of Curtius, the serotonin levels were measured multiple times, so it is reasonable to assume that the first measurement is a baseline reference point. The first measured serotonin point is 30 umoles per mole of creatinine, which is within the "normal range" at the bottom of the table. This corresponds to 46.7 ug of serotonin per gram of creatinine, assuming a molecular weight of 176.22 for serotonin and 113.12 for creatinine. Claim 19 is rejected because it requires no steps beyond claim 1 and the reference teaches that all measured values of serotonin are within the normal/optimal range of 22 – 60 umoles/mole of creatinine. Claim 24 is rejected because the term "outside a reference range" has no limitation. Whether or not the point is within or outside a "reference range" depends entirely on what that range is. Here, it is not defined by the claim, and clearly the values obtained are outside of certain ranges such as the range of 100 – 200 umoles per mole of creatinine. Claim 25 is rejected because a) it is essentially without limits, as anything can be a therapeutic point and b) Table 1 of the reference clearly shows the level of neurotransmitters after therapeutic treatment, so it must be a "therapeutic point". Claim 26 is rejected because the therapeutic range is not defined, and the Curtius reference clearly discloses that desired values for serotonin are within the range of 22 – 60 umoles/mole. The assayed values are all within the range, so they are therapeutic because they are within the normal range.



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10. Claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 37 – 39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Ross (1999. The Diet Cure. New York:Viking, pp. xxi – xxii, 117 – 130, 355-356).

Ross teaches methods of reducing weight by administering neurotransmitter amino acid precursors. While many of the claims under examination are generic with respect to disease, applicant has elected “obesity” for prosecution on the merits. The specification does not contain an explicit, limiting definition of obesity. The condition is commonly understood to be characterized by excessive body weight. While the book by Ross is not specifically on point to obesity per se, it is on point to weight loss in general. As obesity is characterized by excessive weight, and the reference teaches methods of weight loss (see for example p. xxi, first sentence, which begins “My goal in this book is to stop your food cravings, address your eating and weight problems...”), the entire book is on point to treatment of obesity.

Ross teaches methods of assaying urine and blood plasma levels for neurotransmitter levels (see paragraph spanning pp. 128 – 129). The specific neurotransmitters to be assayed are described in detail throughout the book, and include serotonin. See for example pp. 120 – 121, Amino Acid Therapy Chart, specifically Section V; and pp. 122 – 127, “Raising Serotonin, Our Natural Prozac”. Thus when Ross teaches the reader that blood and urine can be assayed for the neurotransmitters (amino acids), this clearly encompasses serotonin. As the methods of the book are to be performed for weight loss, the health status of the individual has been determined. While Ross does not use the exact words “neurotransmitter status point”, test results are to be obtained and thus how she defines the result does not affect the patentability of the claim. The prior art reference teaches every step recited in claim 1 and thus anticipates the claimed method.

Claim 2 is rejected as the entirety of the book is directed to the humans who are reading it. Note the frequent use of “you” and “your” throughout the cited text. Claim 4 is rejected because the book is on point to weight loss, and thus the health status of the subject is determined with respect to excessive weight or obesity. Claims 5 and 7 are rejected because on p. 128 the reference specifically teaches measuring the levels in both blood, which comprises serum, and urine. Claim 10 is rejected because Ross clearly has contemplated measuring serotonin, which is the neurotransmitter discussed right before the discussion of testing for neurotransmitters.

On pp. 355 – 356, Ross discusses an overall plan for the methods and includes “get testing done” before carrying out the method. Thus this is a “baseline reference point” and thus anticipates claim 13. As claim 14 does not specify any range, no matter what result is obtained it will necessarily be within some reference range; thus the teachings of Ross anticipate claim 14 as well. Similarly, claim 19 requires the value obtained to be within some optimal range, but this is not defined. Thus any value obtained is within some “optimal range” and therefore the reference anticipates claim 19 as well. Likewise, claim 24 is rejected because the baseline reference point is outside at least some “reference range” since this term could be anything and is not defined in the specification in a limiting fashion. Similarly, claim 25 requires that the neurotransmitter status point “is a therapeutic point”. As set forth in the rejection under 35 USC 112, second paragraph above, this does not set forth the metes and bounds of the invention and therefore could be anything. Claim 26 requires that the therapeutic point is within a therapeutic range, and again this range is not set forth in the claim. As any value obtained will be within some set of ranges, the method of Ross anticipates claims 25 and 26 as well.

Claim 37 requires performing a first assay, administering an amino acid precursor of a neurotransmitter, administering a second assay to determine whether the neurotransmitter levels are within “a predetermined range”. Ross teaches administering amino acid precursors to the patients as a treatment for obesity. See for example pp. 122 – 123, which teaches administration of L-tryptophan, and teaches that L-tyrptophan creates serotonin. This section also teaches administration of 5-HTP, “which is a chemical halfway between tryptophan and serotonin” (see p. 123, first complete paragraph) and also teaches specific foods which are high in tryptophan (see p. 123, final paragraph, proceeding onto p. 124). Additionally, Ross teaches that one can test amino acid levels both before and three months after starting taking amino acids (see p. 129, bullet point number 5). Thus Ross teaches both of the assaying steps as well as the administration of amino acid precursors of the neurotransmitter and anticipates claim 37. Claim 38 encompasses obesity and as set forth above the entire book concerns weight loss, thereby meeting the limitation of claim 38. As explained above, Ross teaches (pp. 128 – 129) testing of both blood and urine, which anticipates claims 39 and 41.

***Claim Rejections - 35 USC § 103***

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11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 33, 37 – 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross.

The reasons why claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 37 – 39, and 41 are anticipated are set forth in the rejection under 35 USC § 102 above. Briefly, Ross teaches assaying body fluids for serotonin levels, wherein the method is to be performed in persons needing weight loss therapy. Ross also teaches administering amino acid precursors to the patients as a treatment for obesity and assaying neurotransmitter levels twice. However Ross does not teach “graphing the neurotransmitter level over time” as recited in claim 33.

It would have been obvious to one of ordinary skill in the art to graph the neurotransmitter level over time, with a reasonable expectation of success. The motivation to do so would be to provide a format for the data which is easily understood. Graphing is well-known to allow for rapid interpretation of complex data.

12. Claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 33, 37 – 39, 41 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross as applied to claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 33, 37 – 39, and 41 above, and further in view of Curtius et al. (U.S. Patent 4,774,244, issued 27 September 1988).

The reasons why Ross either anticipates or renders obvious claims 1 – 2, 4 – 5, 7, 10, 13 – 14, 19, 24 – 26, 33, 37 – 39, and 41 are set forth in the rejections under 35 USC §§ 102 and 103 above. Briefly Ross teaches assaying body fluids for serotonin levels, wherein the method is to be performed in persons needing weight loss therapy and teaches administration of amino acid precursors of serotonin to patients. However Ross does not teach collecting urine for assay 5 – 6 hours before bedtime, as recited in claim 42, or measuring micrograms of neurotransmitter per gram of creatinine as recited in claim 43.

Curtius teaches measurement of serotonin in the urine of a patient with inhibited depression (see Table 1). Curtius also teaches that urine samples were collected at 0, 2, 4, 8 – 10, and 12 hours. While the reference is silent as to the patient's bedtime and the actual time of collection,

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any one of these points reasonably falls 5 – 6 hours before the patient's bedtime. For instance, if the patient's bedtime is 11PM, and the first sample is collected at 9 AM, then 8 – 10 hours later is 5PM – 7 PM, which is within the range of 5 – 6 hours before the bedtime and is on point to claim 42. The results are expressed in umoles of neurotransmitter per mole of creatinine (see table). While this is not "per gram of creatinine" as recited in claim 43, the values are easily converted and said conversion does not distinguish the invention of claim 43 from the prior art.

It would have been obvious to one of ordinary skill in the art to modify the method of Ross and obtain a urine sample 5 – 6 hours before the subject's bedtime, as taught by Curtius. The motivation to do so would be to select a time point that is convenient to the subject and allows for accurate measurement of the neurotransmitter. It would also be obvious to measure the neurotransmitter in micrograms of neurotransmitter per gram of creatinine, as Curtius teaches it is appropriate to normalize to creatinine levels, and converting from umoles per mole to micrograms per gram is a trivial mathematical operation.

### ***Conclusion***

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Daniel E. Kolker, Ph.D.

June 15, 2006



**ROBERT C. HAYES, PH.D.**  
**PRIMARY EXAMINER**